

### **Remarks**

Upon entry of this response, claims 1-14, 16, and 31-33 will be pending in this application. Claims 7 and 9-14 were previously withdrawn as encompassing non-elected subject matter. With this response, Applicants have cancelled claims 15 and 30 and amended claim 1 to replace “an immunologic disorder” with “an autoimmune disorder.” Support for this amendment may be found throughout the specification as filed, e.g., at paragraph [0002].

### **Interview Summary**

Applicants wish to thank Examiners Chandra and Landsman for the courtesy extended to Applicants’ representatives in a telephone interview on February 3, 2010, concerning the finality of the Office Action issued November 23, 2009. At the conclusion of the interview, the Examiners agreed to withdraw the finality, as reflected in the current Office Action.

### **Enablement**

The Examiner has rejected claims 1-6, 8, 15, 16, and 30-33 under the first paragraph of 35 U.S.C. § 112 as allegedly lacking enablement. The Examiner acknowledges that the specification enables a method of treating a patient having an autoimmune disease comprising administering an antibody that binds to SEQ ID NO: 1, but asserts that it does not enable treatment of “any immunological disorder comprising administering an antibody that binds to the polypeptide of SEQ ID NO: 1<sup>1</sup>. Office Action of February 17, 2010, at 6.

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<sup>1</sup> The Office Action refers to methods comprising administration of an antibody that binds to SEQ ID NO: 2, but this appears to be a typographical error. The claims recite an antibody that binds to SEQ ID NO:1.

Without acquiescing to the rejection of the previously pending claims, Applicants have cancelled claim 15 and amended claim 1 to recite “a patient having an autoimmune disorder.” As noted above, the Examiner has acknowledged that the specification enables treatment of an autoimmune disorder<sup>2</sup>. Accordingly, Applicants respectfully request that the enablement rejection be reconsidered and withdrawn.

### **Nonobviousness**

The Examiner has also rejected the claims as allegedly obvious over (1) Ruben et al. (U.S. Patent No. 7,112,410) in view of Brenner et al. (U.S. Patent No. 5,445,940) and (2) Ambrose et al. (U.S. Patent No. 7,112,421) in view of Brenner et al. (U.S. Patent No. 5,445,940).

Applicants respectfully submit that the Office Action fails to state a prima facie case of obviousness based on either combination of references. The claimed methods include the step of temporarily discontinuing the administration of antibody for N weeks or longer, wherein N is 8, 9, 10, 11, or 12, then resuming the administration. The Examiner acknowledges that neither Ruben nor Ambrose teaches temporarily discontinuing the administration as claimed. The Examiner attempts to use Brenner as evidence that it would have been obvious to modify the methods of Ruben or Ambrose to arrive at those now claimed. Even by the Examiner’s reasoning, however, Brenner fails to cure the deficiencies of Ruben and Ambrose. Applicants note again that the claims require discontinuing administration for at least 8 to 12 weeks. The Examiner asserts only that Brenner teaches “interruption intervals of three days to a couple of

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<sup>2</sup> Applicants also note that the enablement rejection does not apply to claim 30 (now cancelled) and claims 31-33. These claims do not recite treatment of an immunologic disorder, which was the sole basis provided for the enablement rejection.

weeks.” Office Action of February 17, 2010, at 8, citing Brenner, col. 17, lines 15+.

Later, the Examiner acknowledges that Brenner teaches “an interval of two weeks.” *Id.* at 9. The Examiner has not identified any reason that the skilled artisan would discontinue treatment for at least four times as long as the interval taught by Brenner. The Examiner also fails to provide any evidence that the skilled artisan would reasonably expect that the patient could be successfully treated with an interruption interval so much longer than that taught by the cited art.

Even if Brenner taught discontinuing administration for 8 to 12 weeks or longer (which it does not), it still would not render the claimed methods obvious. As noted at paragraph [0009] of the instant specification, once the administration has ceased and the agent is eliminated from the bloodstream, “B cell reconstitution to pre-treatment levels, including recovery of pathogenic B cells, is expected to occur within about 8 weeks. As a result, frequent administration of these drugs, at intervals of less than 8 weeks, may be necessary to maintain therapeutic benefits” (citations omitted). Brenner does nothing to overcome that expectation, because it does not relate to B cells. The agent to be administered in Brenner’s methods is specific to T cells. See column 1, lines 23-26. Similarly, the data in Brenner relates solely to T cells. Thus, Brenner does not suggest that administration of an agent that targets B cells, such as the anti-BAFF-R antibodies recited in the pending claims, may be discontinued for 8 weeks or longer.

Applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

**Conclusion**

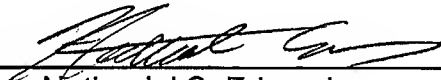
In view of the foregoing remarks, Applicants believe that the claims are in condition for allowance. The Examiner is urged to call the undersigned with any questions at (617) 452-1669.

Please grant any additional extensions of time required to enter this response and charge any additional fees to deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By:   
Nathaniel S. Edwards  
Reg. No. 57,745  
Tel.: 617.452.1669